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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,791	11/05/2001	Perry G Caimi	BB-1356USPCT	5803

23906 7590 06/02/2004

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 WILMINGTON, DE 19805

EXAMINER

BUI, PHUONG T

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/009,791	<b>Applicant(s)</b> CAIMI ET AL.	
	<b>Examiner</b> Phuong T. Bui	<b>Art Unit</b> 1638	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/5/01</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. The Office acknowledges the receipt of Applicant's restriction election filed April 5, 2004. Applicant elects Invention I and SEQ ID NO:21 encoding SEQ ID NO:22 without traverse. Claims 21-33 are pending and are examined in the instant application. This restriction is made FINAL.

### ***Information Disclosure Statement***

2. A dated and initialed copy of Applicant's IDS is attached to the instant Office action.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 21-24 and 27-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The metes and bounds of "coronatine-induced activity" cannot be determined based upon Applicant's disclosure. The specification does not provide a definition for "coronatine-induced activity".

Furthermore, page 1 of the specification discloses that the gene is induced by coronatine, i.e., is acted on by coronatine. However, it is unclear what the claimed polynucleotide does in response to being acted on, e.g., what reaction it catalyzes, what gene(s) it turns on, etc. Thus, "coronatine-induced activity" does not indicate what activity the claimed polynucleotide has, but rather describes the activity of another compound, coronatine. Without knowing what activity the claimed polynucleotide has,

one cannot determine the metes and bounds of sequences having less than 100% sequence identity with the claimed sequence. Correction or clarification is required.

***Claim Rejections - 35 USC 101 Utility***

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 21-33 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well-established utility. The claimed invention does not meet the utility requirements under current utility guidelines. First of all, Applicant does not disclose that SEQ ID NO:21 encodes a complete protein; and SEQ ID NO:21 does not appear to contain a complete open reading frame since it does not begin with the start codon methionine. Neither Applicant's disclosure nor the state of the prior art at the time the invention was made provides guidance as to where the catalytic domain(s) of Applicant's "coronatine-induced" protein is located. Again, as indicated in the 112, 2<sup>nd</sup> paragraph rejection above, the "coronatine-induced activity" only indicates that coronatine may act on SEQ ID NO:22, and does not indicate what SEQ ID NO:22 acts on once it is induced by coronatine. So while the complete protein may inherently possess some kind of activity, such as disease resistance, it is unclear that the disclosed polypeptide contains the necessary domains for that activity, as it does not appear to be a complete sequence. No empirical data are presented to verify that SEQ ID NO:21 or a nucleotide sequence encoding SEQ ID NO:22 has activity of any kind. While empirical data are not required, sequence alignment is generally useful in placing a protein in a particular class but does not replace verification of function.

Table 5 (p. 22) shows that SEQ ID NO:22 has 67.7% sequence identity with a COI1 sequence obtained from *Arabidopsis thaliana*. However, it is unclear whether the prior art sequence used for sequence alignment with Applicant's SEQ ID NO:22 is a complete protein, and what the sequence identity would be if both the prior art sequence and Applicant's sequence are complete COI1 proteins. Since SEQ ID NO:21 encodes a partial protein and does not contain the catalytic domain(s) necessary for function, the utility for such a sequence would be lacking. It would also follow that sequences having less than 100% sequence identity to SEQ ID NO:22 would lack utility for the same reasons.

Secondly, assuming *arguendo* the polynucleotide contains the necessary domains for COI1 functions, the claimed invention lacks substantial utility because Applicant does not disclose how SEQ ID NO:21 or a sequence encoding SEQ ID NO:22 can be used to achieve disease resistance. The specification addresses the utility issue only to the extent that "manipulation of the COI1...[gene] will be useful in engineering broad spectrum disease, insect and stress resistance (sentence spanning pages 1 and 2). Applicant does not teach whether the expression of SEQ ID NO:21 should be increased, decreased or inhibited to achieve disease resistance, or how SEQ ID NO:21 should be manipulated otherwise. The Benedetti et al. reference cited by Applicant (Plant Physiol., Vol. 116, 1998, p. 1037-1042 (Applicant's IDS)) teaches a coronatine-insensitive mutant *Coi1*, but it is unclear whether a mutation is also desired in Applicant's claimed polynucleotide, where the mutation(s) should be, and how the mutation would correlate with disease resistance. It is apparent that extensive further

research, not considered to be routine experimentation, would be required before one skilled in the art would know how to use the claimed invention. It has been established in the courts that a utility that requires or constitutes carrying out further research to identify or reasonably confirm a "real world" context of use is not a substantial utility:

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point--where specific benefit exists in currently available form--there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." (*Brenner v. Manson*, 383 U.S. 519 (1966)).

While disease resistance is of substantial benefit to the public, it is unclear how a nucleotide sequence having "coronatine-induced activity" can be used to achieve any substantial benefit. Applicant's claimed invention is not refined and developed to the point where specific benefit exists in currently available form. As set forth above, one skilled in the art cannot readily take Applicant's claimed invention and achieve the asserted utility based upon Applicant's disclosure. Accordingly, the claimed invention lacks a "real-world" use, or lacks substantial utility.

Additionally, there is no well-established utility for SEQ ID NO:21 and a sequence encoding SEQ ID NO:22. SEQ ID NO:21 does not have a well-established utility for hybridization purposes because the encoded protein does not have utility for the reasons indicated above. Thus, for the reasons set forth, the claimed sequences lack utility (see Utility Examination Guidelines published in Federal Register/ Vol. 66, No. 4/ Friday, January 5, 2001/ Notices; p. 1092-1099).

***Claim Rejections - 35 USC § 112, first paragraph***

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7. Claims 21-33 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Additionally, claims reciting less than 100% sequence identity are not enabled because they encompass unspecified base deletions, additions, substitutions, and combinations thereof while retaining "coronatine-induce activity". Applicant provided no working examples or further guidance as to which region(s) of SEQ ID NO:21 are conserved domains necessary for protein activity. While skilled in the art can readily make base changes, further guidance is necessary as to what changes would be tolerated. Also, since it is unclear what the claimed activity encompasses (see 112, 2<sup>nd</sup> paragraph rejection above), one skilled in the art would not be able to determine which sequences would have the desired activity, and how to eliminate inoperable embodiments without undue experimentation. Accordingly, the claimed invention is not enabled.

8. Claims 21-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection. The claims are drawn to an isolated polynucleotide comprising a nucleotide sequence encoding a polypeptide having less than 100% sequence identity to SEQ ID NO:22. However, the translated amino acid sequence SEQ ID NO:22 appears to be only a

partial sequence of a protein (see utility rejection above). SEQ ID NO:21, which encodes SEQ ID NO:22, is only a partial gene sequence and does not contain a complete open reading frame encoding a complete protein. However, the “comprising” language in the claims reads upon complete gene sequences having in common a nucleotide sequence encoding SEQ ID NO:22. There are insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine the complete structure of a gene encoding a coronatine-induced or COI1 protein based upon the disclosure of a partial sequence, absent further guidance. Accordingly, one skilled in the art would not recognize from Applicant’s disclosure of SEQ ID NO:21 that Applicant is in possession of the complete gene encoding a complete a coronatine-induced or COI1 protein.

The claims reciting less than 100% sequence identity lack adequate written description because Applicant does not disclose a representative number of species as encompassed by these claims. The claims encompass mutants and allelic variants and thus imply that structural variants exist in nature, yet no structural variant has been disclosed. The claims also encompass “coronatine-induced” proteins from other species. The implication is that there is a gene and a protein other than that disclosed which exists in nature, but the structure thereof is not known. Applicant discloses a single sequence SEQ ID NO:21 isolated from *Glycine max*. Thus, there are insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine such mutants, allelic variants and coronatine-induced proteins from other plants and organisms, absent further guidance. Accordingly, there is lack of adequate description



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to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/ Vol.66, No. 4/ Friday, January 5, 2001/ Notices; p. 1099-1111.

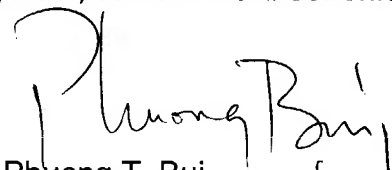
**Remarks**

9. No claim is allowed. SEQ ID NO:21 and a nucleotide sequence encoding SEQ ID NO:22 are free of the prior art. It is understood by the Office the Clustal alignment method uses the default parameters set forth on page 23, lines 3-5 of the specification. The closest prior art teaches a sequence isolated from *Arabidopsis thaliana* having 67.7% sequence identity with SEQ ID NO:22 (Table 5, p. 22 and Dao-Xin Xie et al., Science, Vol. 280:1091-1094, 1998 (Applicant's IDS)).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong T. Bui whose telephone number is 571-272-0793. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Phuong T. Bui  
Primary Examiner  
Art Unit 1638  
5/17/04

5/17/04